UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,430	09/21/2000	Delphine Gabrielle Josette Rea	4205.1US	6289

24247 7590 10/09/2007

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
10/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	09/666,430	REA ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 40-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *64 and 69-81* is/are allowed.

6)☒ Claim(s) *1,40-49,51-53,55,56,58,59,61-63 and 65-68* is/are rejected.

7)☒ Claim(s) *50,54,57,60 and 67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070705*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

Claims 2-39 were previously canceled.

Claims 1 and 40-81 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's Appeal Brief filed on August 14, 2006 (in part) and October 11, 2006 (in part) has been entered.

In view of Applicant's arguments presented in the Appeal Brief filed August 14, 2006 (in part) and October 11, 2006 (in part) the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

2. Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth previously, there is insufficient written description to show that Applicant was in possession of "means for reducing IL-12p40 production by said dendritic cell." As said "means" comprise an unknown genus of indeterminate size, one of skill in the art must conclude that the specification fails to disclose an adequate written description or a representative number of species to describe the claimed genus.

Applicant's arguments, filed August 14, 2006, have been fully considered but they are not persuasive. Applicant again cites 35 U.S.C. 112, paragraph six. Applicant is again advised that no rejection under 35 U.S.C. 112, paragraph six has been made.

Applicant asserts that the present claim should not be subject to the written description requirements of 112, 1 because the claim falls under the auspices of 112, 6. Applicant argues that the claim meets the three-prong test of 112, 6 and therefore should be allowable. Applicant points out that the claim recites a "means for" performing a function (first prong) and that the "means for" is modified by functional language (second prong).

Applicant argues that the disclosure of dexamethasone (Dex) is a sufficiently representative example of glucocorticoids and therefore meets the third prong. The Examiner disagrees. The third prong of 112, 6 states that the claim "shall be construed to cover the **corresponding structure, material**, or acts **described in the specification** and **equivalents thereof**" (emphases added for clarity). The only "structure" or "material" that is "described in the specification" is Dex. Accordingly, there are no other structures or materials in the specification as originally filed for Dex to cover as "a means for reducing IL-12p40 production." Therefore, Applicant must rely upon Dex being sufficient to cover "equivalents thereof" in order to meet the third prong of 112, 6. However, the actions of the genus "glucocorticoids" are sufficiently divergent that a description of the single species "Dex" is not deemed to be representative of the genus to support a recitation of a "means for reducing IL-12p40 production." All experiments in the specification have been performed employing dexamethasone (Dex) exclusively. It is again noted that Applicant's own submission, Glucocorticoids from Stanford's HOPES project (of record), teaches that not all glucocorticoids comprise the same biological activities. Dex is described as having more anti-inflammatory activity than prednisone or hydrocortisone, and hydrocortisone is described as having more undesirable activity than either Dex or prednisone. The teaching echoes what has been well known in the art for some time, i.e., that glucocorticoids comprise different biological activities in different contexts, see for example Bray et al (1978, of record).

Accordingly, not even other glucocorticoids can be considered to be "equivalents" that can be covered by Dex in the context of the claim under the third prong of 112, 6. therefore, claim 1 is not

entitled to the invocation of 112, 6 and remains rejectable under the written description provisions of 112, 1 for the reasons made of record.

The following represent NEW GROUNDS of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40-49, 51-53, 55, 56, 58, 59, 61-63, 65-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preparing a loaded, activated dendritic cell or a composition comprising same by treating the cells with Dex, does not reasonably provide enablement for a method for preparing a loaded, activated dendritic cell or a composition comprising same by treating the cells with glucocorticoids in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The data disclosed in the instant specification provides insufficient support for scope of the method of the instant claims. *In vivo* data is not required, however, an enabling specification is required. The sole relevant example in the specification does not support the scope of the instant claims. Example 4 merely discloses that a T cell response to a known antigen can be reduced employing a single known immunosuppressive drug (Dex). The Inventor's declaration filed November 21, 2003 provides little additional enablement for the claimed method. Example 1 teaches that an *in vitro* alloimmune T cell response (MLR) can be suppressed employing Dex-treated DC. Example 2 teaches that a

long term cultured Dex-treated DC (not a cell that could be employed for *in vivo* treatment) could reduce an allo-response.

However, disclosure of the species Dex is not representative of a general recitation of the genus glucocorticoids. It is again noted that Applicant's own submission, Glucocorticoids from Stanford's HOPES project (of record), teaches that not all glucocorticoids comprise the same biological activities. Dex is described as having more anti-inflammatory activity than prednisone or hydrocortisone, and hydrocortisone is described as having more undesirable activity than either Dex or prednisone. The teaching echoes what has been well known in the art for some time, i.e., that glucocorticoids comprise different biological activities in different contexts, see for example Bray et al (1978, of record). Accordingly, the genus "glucocorticoids" is not adequately represented by the species "Dex" and the scope of the claim is therefore not supported by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's recitation of "means for reducing IL-12p40 production by said dendritic cell", is intended to invoke the special claim interpretation provisions of 35 USC 112 sixth paragraph. In turn, claim 1 is rejected under 35 USC 112 second paragraph.

In order for a claim to meet the particularity requirement of 35 USC 112 second paragraph, the corresponding structure(s) of a means-plus-function limitation must be disclosed in the written description in such a manner that one skilled in the art will know and understand what structure corresponds to the means limitation.

Regarding the means-plus-function limitations recited in the instant claim, i.e., "means for reducing IL-12p40 production by said dendritic cell", there does not appear to be any structure in the specification corresponding to these means-plus-function limitations in the claims.

Therefore, "[i]f there is no structure in the specification corresponding to the means-plus-function limitation in the claims, the claim will be found invalid as indefinite." *Biomedino LLC v. Waters Technologies Corp.*, 83 USPQ2d 1118, 1121 (Fed. Cir. 2007).

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter. See MPEP 714.02 and 2163.06.

Conclusion

6. Claims 50, 54, 57, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 64 and 69-81 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
September 29, 2007

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER